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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/031,922

Applicant(s)

GAYED, ATEF

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1,2 and 42-44 is/are allowed.
- 6) ☐ Claim(s) 16,29-41 and 45-52 is/are rejected.
- 7) ☐ Claim(s) 3-32 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**CLAIMS 1-52 ARE PRESENTED FOR EXAMINATION**

Applicant's Information Disclosure Statement filed January 7, 2003 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (2 pages), the cited references have been considered.

***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Claim Objection***

Claims 3, 5, 8, 10, 12, 16, 18, 20, 22, 24, 26-29, 31, 32, 36 are objected to as being in improper dependent form because they fail to refer back to a previous claim. See MPEP 6.08.01 (i) citing 37 CFR 1.75.

Claims 4, 6, 7, 9, 11, 13-15, 17, 19, 21, 23, 25, 30 are objected to because they depend from the claims above which are objected to as being in improper dependent form.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 29-41 and 45-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergamini et al. (U.S. Patent No. 5,597,560).

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Bergamini et al. teaches a pharmaceutical composition comprising diclofenac (a topical agent or a second active agent as per applicant's claim Nos. 29 and 30 (for example)) and tobramycin (an antimicrobial as per applicant's claim No. 16 (for example) in the form of a solution which may contain benzethonium chloride and phenoxy-ethanol as preservatives used to inhibit microbial contamination of the product. See the abstract, column 4, lines 10-13 and column 5, lines 22, 23, 26, 30 and 31. The preservatives may be present in a range of from 0.005% to about 5.0%. See column 4, line 34. The composition may be applied aurally, i.e., in the ear or optically (as per applicant's claim 32, for example) or ocularly, i.e., in the eye or ophthalmically (as per applicant's claim 32, for example).

The difference between the above and applicant's claimed subject matter lies in that the patentees do not highlight the specifically claimed benzethonium chloride and phenoxy-ethanol concentrations (see, e.g., present claim 38), a vial (see, e.g., present claim 37) or a pharmaceutical package (see, e.g., present claim 40).

However, to the skilled artisan, the claimed subject matter would have been obvious because the claimed ingredient ranges are well within the concentration ranges disclosed by the patentees and the determination of the optimum concentrations to employ would have been a matter well within the purview of the skilled artisan who would have been motivated to do so in order to provide a composition with the most effective preservative effect possible. Also, vials and multi-dose packaging systems were well known means of packaging pharmaceuticals and the selection of any one particular packaging means from those known would have also been a matter well within the purview of the skilled artisan.

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Concerning present claims 33 and 48, the Examiner is interpreting the phrase "for use as a non-topically administered carrier" as merely a statement of intended use and not a limitation as to the physical characteristic of the composition.


***Allowable Subject Matter***

Claims 1, 2 and 42-44 are deemed to be in condition for allowance because as set forth in the Merck Index (submitted by applicant), cit. #'s 1083 and 7226, benzethonium chloride and phenoxy-ethanol were known as topical agents and thus, with the exclusion of the topical formulations taught by Bertamini et al. (U.S. Patent No. 5,597,560), one would not have been motivated to employ benzethonium chloride and phenoxy-ethanol in a composition of present claim 1, which requires that the composition is not formulated for topical administration or to inhibit microbial growth in a non-topically-administrable solution by placing benzethonium chloride and phenoxy-ethanol in such a solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 703-308-4652. The examiner can normally be reached on Flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Raymond J. Henley III  
Primary Examiner  
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